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Drug residues in food animals

W. R. Van Dresser, DVM, and J. R. Wilcke, DVM, MS

Preface

With the following report, we intend to provide an accurate image of the current situation regarding animal drug residues in food animals. We include assessments of cause, amount of involvement for various production classes, profiles of the therapeutic regimens for the drugs involved, indications of labeling and veterinary instruction, relationships to regulatory descriptions, and the relative frequency of responsibility assigned to the various segments of the food animal industry (eg, producer, veterinarian, auction barns).

This report is derived from 2 kinds of information. First, we have made an independent compilation of field investigations conducted by FDA/CVM and the Office of the State Veterinarian, VDACS. The field investigations were based on residues detected through one of the USDA/FSIS residue-testing programs on food animals in normal marketing channels. Investigations were conducted by FDA/CVM on the basis of information provided by USDA. Second, this report is a broad review of the available literature on the subject of drug residues. Most of this literature comes from studies conducted by regulatory agencies with authority for drug residues (USDA/FSIS, CVM/FDA, and State Departments of Agriculture).

One precaution must be made before this report is used as a reference for decision making. Specific cases for field investigation were selected, by means unknown to us, by individuals who were not involved in our study. We do not assert that the data were gathered in a random and unbiased fashion. The data were not gathered for the purpose of our analysis. We are also aware that bias is difficult to avoid in an investigation of this type. The use to which data will be put (eg, regulatory, marketing, demographic) may affect its relationship to the population as a whole. If the USDA/FSIS identifies a problem market class, FDA/CVM reasonably draws a sample from the population that emphasizes this market class during certain periods, for certain geographic locations, or for certain slaughter plants. We do believe that the information contained herein is, in fact, representative of the residue situation as it exists in the "real world," and believe that comparison of independent surveys would support this conclusion.

We make no attempt to lend the weight of statistical analysis to our discussions. We have proposed hypotheses, rather than stated conclusions, because of the necessary limits imposed by the source(s) and magnitude of the data. These limits are acknowledged in the report where appropriate.

It would be a disservice to those who undertake to solve the problems associated with drug residues in food animals if the report were taken out of context or if the findings were interpreted in a manner that went beyond the restrictive boundaries of logic and reason. This strong precaution is not to convince the reader that the report will not be useful in giving insights or confirming empirically derived conclusions as to the nature, extent, and causes of drug residues in food animals. Rather, the report cannot be applied to the whole universe of drug residues. This is not a scientific investigation of drug residues in food animals. It is an accounting of a situation within a dynamic industry that, for much of the information this study provides, has been sampled in a limited way.—W. R. Van Dresser and J. R. Wilcke

Summary: *A total of 292 field investigative reports of drug residues in food animals for 1983 to 1988 were analyzed. The investigations had been conducted by the Food and Drug Administration (FDA) and the Virginia State Veterinarian's Office, in cooperation with the Center for Veterinary Medicine of the FDA, to trace residues reported by the USDA Food Safety and Inspection Service to the source of the animal and the administration of the drug.*

The analysis disclosed the following. (1) Antibiotic residues were most often associated with streptomycin, penicillin, oxytetracycline, and neomycin. Sulfamethazine was, by far, the most frequently cited sulfonamide. (2) Residues are being found predominantly in cows, veal calves, and market hogs (barrows and gilts). (3) The cause of drug residue most frequently cited by the field investigators was failure to observe the withholding time for the drug. Almost half of these investigations revealed that the individual responsible for the sale of the animal did not know the proper withholding time for the drug. Failure to maintain adequate records was also a contributing factor. (4) The producer was considered to be the responsible party in over 80% of the cases for which responsibility was determined. (5) Residues associated with injectable drugs were investigated most frequently. Long-acting and sustained-release products were most often associated with penicillin and oxytetracycline residues. (6) The 2 most common sources of purchase for the drugs involved in the investigations were the feed/farm supply store and the veterinarian. (7) Unapproved drug use was not a major cause of residues.

Residues of therapeutic and production-enhancing drugs in food products derived from domestic animals are a topic of considerable concern in all dimensions of the food animal industry. Producers and the national organizations that represent them are confronted by consumers who are increasingly aware of the health consequences of the food they eat. This "food consciousness" includes a greater awareness of the production practices that expose food animals to drugs. Negative, inflammatory, and misleading advertising sponsored by the Humane Farming Association has been used to condemn animal husbandry practices in the veal industry.[1] A portion of this advertising has been directed at the use of antimicrobials in the veal industry. The sponsors of the advertisement suggest that "antibiotic-laced" formulas induce severe diarrhea, "create virulent strains of bacteria that wreak havoc on human health," and leave residues that are directly toxic to human beings.

A strong negative association between antibiotic use and food wholesomeness, accurate or not, reflects on the larger food animal industry. In response, producers are increasing their awareness of the potential regulatory and marketing problems associated with drug residues. At the present time, it is unlikely that one could pick up a journal dedicated to animal production without finding a scientific discussion, editorial, or advertisement that speaks to the problem. The producer is seeking information that can be used to maintain the wholesomeness and marketability of food animal products.

Veterinarians, too, are facing a dramatic change in attitude and behavior concerning drug residues and, in broader context, their therapeutic use of drugs. For too long, veterinarians have paid insufficient attention to the instructions of the producer in the appropriate use of drug products and to the labels placed on drugs. Suddenly, and with increasing frequency, veterinarians are faced with an educated producer who wants assurances that drugs administered will not result in residues at the time of sale. The veterinarian needs information to address this problem in a correct and useful way. Abilities in diagnostic medicine and therapeutics, demographic and scientific research, residue testing and consultation for producers, and client education place veterinarians in a strategic position to influence drug residue incidence in food animals.

Finally, it is clear that the pharmaceutical industry will participate in the changes in the food animal industry as a result of these marketplace events. The current system of drug distribution through both over-the-counter and professional channels may face some revision. In certain cases, specific generic or brand-name items have become associated with the production of excessive numbers of violative residues. It seems likely that this association will be as detrimental to a drug's market share or regulatory safety as would a high incidence of some physical side effect in the treated animal. The association will be built on believable information concerning specific products or practices that lead directly to residues.

Materials and methods

Previously unpublished information included in this report was obtained by the authors from the

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This study was funded by the AVMA.

This report would not have been possible without the full cooperation of a number of government agencies and individuals. We wish to cite the USDA Food Safety and Inspection Service (USDA/FSIS), The Food and Drug Administration's Center for Veterinary Medicine (FDA/CVM), The Virginia Department of Agriculture and Consumer Services (VDACS), Division of Animal Health, Office of the State Veterinarian, Division of Dairy and Foods; and the USDA Extension Service. The following individuals within these agencies were especially helpful: Dr. Lester Crawford, Dr. W. R. Miller, and Dr. John Honstead from the USDA/FSIS; Dr. Gerald Guest, Dr. Richard Teske, Dr. Joseph Paige, and Dr. Richard Talbot from FDA/CVM; Dr. W. D. Miller, Dr. P. J. Friedman, and Mr. Archie C. Holliday from VDACS.

Center for Veterinary Medicine of the Food and Drug Administration (FDA/CVM) and from the Virginia Department of Agriculture and Consumer Services (VDACS) in cooperation with FDA/CVM. In both cases, investigations were conducted after the detection of a residue through the USDA/FSIS residue monitoring or surveillance programs. The FDA/CVM reports were filed by FDA field personnel from 17 district offices, and were collected by the CVM. The VDACS reports were filed by veterinarians from the Office of the State Veterinarian in Virginia. Archived reports were in narrative form and described the investigator's visit to the production unit.

Summary questionnaires were prepared, and the narrative reports were extracted. All reports filed during calendar years 1986 to 1987 (FDA/CVM) or 1983 to 1988 (VDACS) that were available to us at the time of extraction were included. Extractions were completed by one of the authors or by an individual under subcontract to the authors. Questionnaires were recorded by use of a personal computer and a commercial database program.

Extractions and tabulation of the records were accomplished by use of the same computer and a commercial spread-sheet program that reads the database file directly. Statistical methods were not used in analysis of the data. Results are expressed either as the absolute number of records or residues, or as a percentage of all records or residues. The difference between records and residues comes from the finding of multiple residues in some animals in both studies. Some characteristics seemed to be more directly linked to the individual residue, rather than to the "case" as a whole. For example, when we described the relationship between a generic name and the residue detected, it seemed more appropriate to express results as a percentage of all residues (rather than a percentage of records).

Results

Overview of FDA/CVM and VDACS Field Investigations

Drug and drug product—Incidence of residues by drug was the most accessible and complete information in the 2 studies. This is simply because the residue, as determined by USDA/FSIS, initiates each investigation. The drug residue information is rarely (3.7% in the combined studies) unavailable. Drugs most commonly involved in residues included streptomycin (20.2% and 19.2%), penicillin (13.1% and 13.1%), sulfamethazine (10.3% and 15.2%), and oxytetracycline (9.1% and 7.1%) in FDA/CVM and VDACS reports, respectively. Table 1 gives the incidence of all residues investigated by FDA/CVM investigators and by veterinarians of the VDACS. Investigations that did not report a specific residue, such as unidentified microbial inhibitor or calf antibiotic and sulfonamide test, are also included.

Table 1—Incidence of particular drug residues in the tissue residue field investigation database.

	FDA/CVM		VDACS	
Residue	**No.**	**(%)**	**No.**	**(%)**
None	11	(4.4)	2	(2.0)
Antibiotics	16	(6.3)		
Penicillin	33	(13.1)	13	(13.1)
Streptomycin	51	(20.2)	19	(19.2)
Tetracycline	8	(3.2)	2	(2.0)
Tylosin	2	(0.8)		
Erythromycin	2	(0.8)	1	(1.0)
Neomycin	22	(8.7)	4	(4.0)
Oxytetracycline	23	(9.1)	7	(7.1)
Chlortetracycline	3	(1.2)	3	(3.0)
UMI	22	(8.7)	10	(10.1)
Gentamicin sulfate	13	(5.2)	5	(5.1)
Zearalanol	1	(0.4)		
Zearalenone	2	(0.8)		
Sulfonamides	9	(3.6)		
Sulfadimethoxine	4	(1.6)		
Sulfamethazine	26	(10.3)	15	(15.2)
Sulfamerazine	1	(0.4)		
Sulfathiazole	1	(0.4)	1	(1.0)
Sulfamethiazole			1	(1.0)
Halofuginone	2	(0.8)		
CAST			16	(16.2)
Total	252		99	

UMI = Unidentified microbial inhibitor. CAST = Calf antibiotic and sulfonamide test.

Trade names were also recorded in a limited number of reports within the FDA/CVM database. Ninety-two of 252 (FDA/CVM) and 69 of 100 (VDACS) residues were associated with enough information to determine either the generic or trade name of the drug product administered. Table 2 lists the generic names associated with residues for the 4 most common residues found in the 2 surveys. Penicillin residues were associated with sustained-release penicillin products, either alone or in combination with other drugs. Of 16 streptomycin residues, 14 were associated with the same combination products that led to penicillin residues. For neomycin, 5 of the 6 documented resi-

Table 2—Drug products associated with certain antibiotic residues in field investigations (totals are for both FDA/CVM and VDACS studies and indicate all residues for which this information was known).

Residue investigated	FDA/CVM	VDACS
Penicillin		
Procaine penicillin G (PPG)	5	1
PPG + dihydrostreptomycin (DHSM)	4	10
PPG + DHSM chlorpheniramine (CPHM) + dexamethasone (DXM)	3	1
Benzathine penicillin G (BPG)	2	0
More than one source of penicillin G	1	0
Total	15	12
Streptomycin		
PPG × DHSM	10	4
PPG × DHSM × CPHM × DXM	4	0
PPG × DHSM intramammary suspension	2	0
Total	16	4
Neomycin		
Neomycin sulfamethazine*	2	0
Neomycin sulfate†	4	0
Total	6	0
Oxytetracycline		
Oxytetracyline (long-acting injection)	4	2
Oxytetracycline (injectable)‡	5	3
Total	9	5

*Also associated with sulfamethazine residue. †One oral dose with one iv dose. ‡One report also included with sulfamethazine residue.

dues were associated with oral administration of neomycin. For oxytetracycline, 4 of 9 residues were also associated with a sustained-release product.

Multiple residues—A total of 206 FDA/CVM and 86 VDACS field investigations were analyzed. Multiple residues were found in 18% (FDA/CVM) and 18.6% (VDACS) of the records in the database.

Drug distribution and use: Operations, sources, labeling—A profile of the FDA/CVM study, relative to the type of operation investigated, is shown in Table 3. The study emphasizes the private dairy farm (33.5%), the private on-farm producer of swine, veal, beef, and poultry (32.5%), and buyers and dealers of food animals (15.7%). The other category was almost exclusively slaughter facilities, and these reports generated almost no other data (eg, drug product, route). Operations investigated by either FDA or VDACS field inspectors obtained drug products from several sources (Table 4). In the FDA/CVM reports, the feed and farm supply store (38.9%) and the veterinarian (40.3%) were nearly equal as the dominant sources for the drugs. In the VDACS study, most products were obtained from the same 2 sources, but veterinarians sold fewer of the drugs (20.9%) than did the feed and farm supply store (74.4%).

The label on a drug product is the primary method for distributing therapeutic (eg, dose, indications) and regulatory (eg, dating, purity, ingredients) information, and it is the specific instrument of regulatory enforcement by the FDA. In most cases, the drug product was unavailable for inspection. This was usually a reflection of the time from the detection of a residue until the farm inspection was conducted. At times, the investigation ended at the slaughter plant, and no other information was sought by the field investigator. When the drug was available, an overwhelming majority of the drug products involved were labeled appropriately. Labeling was on 87.2% (FDA/CVM) and 80.6% (VDACS) of the drug products implicated in all reports when the information was available (86 for FDA/CVM and 36 for VDACS).

Only the VDACS study included a distinction between over-the-counter (OTC) and restricted (Rx) drugs, made by the investigators in the field. Although we had some trade name information in the FDA/CVM study, this status can change for a given trade name product, and we believed that it was inappropriate to make assumptions as to regulatory status. In the VDACS reports, we found that 81.8% of the drug products involved were OTC and 18.2% were Rx. This latter percentage parallels the percentage of drugs sold through so-called professional channels, as described in the same VDACS reports. We would hasten to point out that veterinarians were sources for OTC drugs in a number of FDA/CVM reports, so this association is by no means complete.

Table 3—Incidence, by type of operation, in tissue residue field investigation database (FDA/CVM database).

Operation type	No.	(%)
Feedlot	9	(4.6)
Poultry flock	0	(0.0)
Dairy farm	66	(33.5)
On-farm producer*	64	(32.5)
Sales barn	3	(1.5)
Buyer/dealer	31	(15.7)
Animal hauler	6	(3.0)
Other	18	(9.1)
Total	197	

Type of operation was unknown in 13 instances.
*Includes beef, swine, poultry, veal.

Table 4—Incidence in tissue residue field investigation database, by known drug source.*

Drug source	FDA/CVM		VDACS	
	No.	(%)	No.	(%)
Veterinarian	29	(40.3)	9	(20.9)
Supply house	3	(4.2)	1	(2.3)
Feed and farm/supply store	28	(38.9)	32	(74.4)
Mobile peddler/truck	6	(8.3)	0	(0.0)
Other	6	(8.3)	1	(2.3)
Total	72		43	

*Drug source was unknown in 138 (FDA/CVM) and 43 (VDACS) instances.

Market class—A complete accounting of market class association with drug residue field investigations is given in Table 5. Residues found in cows (95, FDA/CVM; and 40, VDACS) were investigated most frequently. The incidence in other adult cattle was substantially lower. Residues in veal calves were investigated with the second highest frequency (47 and 13), and barrows and gilts were third most frequently investigated (27 and 5).

Table 5—Incidence of individual market classes in tissue residue field investigation database.

Market class	FDA/CVM		VDACS	
	No.	(%)	No.	(%)
None given	7	(3.4)	1	(1.2)
Bulls	0		1	(1.2)
Steers	6	(2.9)	2	(2.4)
Cows	95	(46.1)	40	(47.6)
Heifers	1	(0.5)	0	
Calves (unidentified)	2	(1.0)	8	(9.5)
Bob veal	47	(22.8)	13	(15.5)
Formula-fed veal	3	(1.5)	2	(2.4)
Non-formula-fed veal	6	(2.9)	11	(13.1)
Barrows and gilts	27	(13.1)	5	(6.0)
Sows	9	(4.4)	1	(1.2)
Turkeys	1	(0.5)	0	
Chickens	2	(1.0)	0	
Total	206		84	

Pharmacologic information: Dose form, route of administration—The potential association between the route of administration and the presence of drug residues was evaluated. Results of this study indicate that injectable drugs are more likely to cause residues. Injectable drugs were associated with 51.3% (FDA/CVM) and 60% (VDACS) of the residue reports. Feed additives were the second most prevalent form in the FDA/CVM reports

(21.4%). Boluses were second most frequent for the VDACS reports (30%). Information on dose forms and routes of administration is given in Tables 6 and 7.

Although numbers are small, other routes of administration pose interesting problems. A number of neomycin residues were associated with the oral administration of neomycin sulfate. This is not consistent with the generally held belief that orally administered aminoglycosides are not absorbed, and suggests the need for further study. In one report, dairy calves fed cow's milk withheld from market because of antimicrobial administration to the cow developed residues. Such use of "mastitic milk" is not, we believe, uncommon.

Identifiable cause—Identifiable causes are those deduced as contributing to drug residues. In many records, more than one cause was linked to the eventual residue. Often, insufficient information was available to suggest a cause for the residues (106 records for the FDA/CVM study and 30 for the VDACS study). A complete account of causes appears in Table 8.

For those records wherein identifiable cause could be determined and traced back to the administration of the drug, failure to observe withdrawal times was the leading cause of illegal residues. In the FDA/CVM data, 36.9% of all records and 69.1% of those wherein the field investigator determined a cause were associated with failure to observe withdrawal time. In the VDACS data, 58.1% of all records and 89.3% of those wherein cause was determined were similarly associated with observation.

Table 6—Incidence of known dose form in tissue residue field investigation database*

Dose form	FDA/CVM		VDACS	
	No.	(%)	No.	(%)
Injectable	60	(51.3)	36	(60.0)
Bolus	18	(15.4)	18	(30.0)
Feed additive	25	(21.4)	3	(5.0)
Water additive	8	(6.8)	2	(3.3)
Intramammary infusion	3	(2.6)	1	(1.7)
Other	3	(2.6)	0	(0.0)
Total	117		60	

*Dose form was unknown in 103 (FDA/CVM) and 26 (VDACS) instances.

Table 7—Incidence of known routes of administration in tissue residue field investigation database*

Route of administration	FDA/CVM		VDACS	
	No.	(%)	No.	(%)
Injection	60	(51.3)	37	(61.7)
Bolus	18	(15.4)	16	(26.7)
Feed	25	(21.4)	4	(6.7)
Intramammary	5	(4.3)	2	(3.3)
Water	5	(4.3)	1	(1.7)
Other	4	(3.4)	0	(0.0)
Total	117		60	

*Route of administration was unknown in 103 (FDA/CVM) and 27 (VDACS) instances.

Table 8—Incidence of primary causes of drug residues as described in tissue residue field investigation database

Primary cause	FDA/CVM	VDACS
Withdrawal time not followed and not known	38	41
Withdrawal time not followed and known	38	9
Label not followed	36	22
Veterinarian's direction not followed	7	
Exceeded dose	2	
Unapproved use	8	2
Poor production practices	16	11
Improper mix of feed	6	7
Fed milk containing drug	2	
Given by mistake	2	1
Wrong feed	3	2
Could not determine	106	30

Failure to maintain records was also associated with illegal residues in 7.7% (FDA/CVM) and 12.8% (VDACS) of the records. Other identifiable causes of illegal drug residues determined in the FDA/CVM and VDACS studies, making up ≤5% of the total, included "exceeded recommended dose, improper mix of feed, fed milk containing a drug residue to calves, and mistaken administration."

The unapproved use of a drug is listed as a cause of violative residues in the residue follow-up report form and is included as a cause in 7.2% (FDA/CVM) and 3.6% (VDACS) of the total reports in each analysis. Unapproved drug use is given as a sole cause in only 1 (FDA/CVM) of the reports. Reports did not distinguish between veterinarians and other drug administrators in this regard.

Responsibility—The individuals who administered the drug product to the animal(s) involved in the residue report are identified in Table 9. Accounting only for those reports wherein this individual was known, the drug involved in the residue was given by the animal owner or someone responsible to the owner in 94% (FDA/CVM) and 98% (VDACS) of the time. Although responsibility was assigned by the investigator in the field, it seems reasonable to conclude that the individual who administers the drug is most often held accountable. This is supported by the assignment of responsibility, as displayed in Table 10. When known, responsibility was assigned to the producer (owner) at rates of 80.8% (FDA/CVM) and 92.5% (VDACS).

Table 9—Incidence of known drug administrator in tissue residue field investigation database*

Who treated?	FDA/CVM		VDACS	
	No.	(%)	No.	(%)
Owner	75	(70.8)	45	(86.5)
Family member	3	(2.8)	2	(3.8)
Hired hand	16	(15.1)	4	(7.7)
Veterinarian	9	(8.5)	0	(0.0)
Animal hauler	0	(0.0)	0	(0.0)
Auction barn employee	0	(0.0)	0	(0.0)
Buyer/dealer	0	(0.0)	0	(0.0)
Other	3	(2.8)	1	(1.9)
Total	106		52	

*Drug administrator was unknown in 101 (FDA/CVM) and 33 (VDACS) instances.

Table 10—Incidence of known responsibility in the illegal residue field investigation database*

Who was responsible?	FDA/CVM		VDACS	
	No	(%)	No	(%)
Producer	84	(80.8)	49	(92.5)
Veterinarian	7	(6.7)	0	(0.0)
Feed mill	1	(1.0)	0	(0.0)
Buyer/dealer	4	(3.8)	2	(3.8)
Mixer/feeder	4	(3.8)	0	(0.0)
Auction barn	0	(0.0)	0	(0.0)
Animal hauler	1	(1.0)	2	(3.8)
Other	3	(2.9)	0	(0.0)
Total	104		53	

*Responsibility was unknown in 104 (FDA/CVM) and 49 (VDACS) instances.

Veterinary Involvement in FDA/CVM-Sponsored Investigations

The sale of the drug product represents the point of contact for the transmission of appropriate information concerning drug use and drug withdrawal times. For this reason and because the question of involvement of a local veterinarian was not elicited directly, we chose to select a subset of records from our original database for which we had a clearly identified source. From the original FDA/CVM data, this included 44 records wherein the source of the drug was a veterinarian and 59 records wherein the source of the drug was a feed store, a cooperative, or some other lay distribution source. The VDACS included only 9 records wherein the veterinarian was the source of the drug, so these data were not analyzed further. Results that follow are taken from the FDA/CVM records only.

Drug and drug product—Drugs investigated in largest numbers included penicillin, streptomycin, neomycin, oxytetracycline, and sulfamethazine. The frequencies of inclusion were roughly similar for either veterinary or lay-source drugs, the major difference being sulfamethazine (Table 11). The generic names of the drugs were similar for either source of drugs. Penicillin residues were nearly always associated with procaine penicillin G administration and streptomycin with some combination of procaine penicillin G and dihydrostreptomycin. Veterinarians were likely to have administered or dispensed a combination of procaine penicillin G, dihydrostreptomycin, and a glucocorticoid. With neomycin, veterinary involvement meant boluses (2 of 3 cases) or injection (1 case), whereas lay distributors favored liquids for oral administration (4 of 5 cases). Sulfamethazine (in this study) was usually given in feed, and feed-additive sulfamethazine was sold by a veterinarian in only one case.

Table 11—Source of generic drugs associated with residues, expressed as an absolute count and as a percentage of the residues from the particular source

Generic drug	Source			
	Veterinarian		OTC	
	No	(%)	No	(%)
Antibiotics	2	(4.5)	2	(4.2)
Penicillin	11	(25.0)	6	(12.5)
Streptomycin	10	(22.7)	8	(16.7)
Tetracycline	2	(4.5)	1	(2.1)
Tylosin	0	(0.0)	1	(2.1)
Neomycin	3	(6.8)	5	(10.4)
Oxytetracycline	4	(9.1)	6	(12.5)
Chlortetracycline	1	(2.2)	0	(0.0)
UMI	3	(6.8)	2	(4.2)
Gentamicin	2	(4.5)	1	(2.1)
Zearalenone	0	(0.0)	2	(4.2)
Sulfonamides	1	(0.0)	2	(4.2)
Sulfadimethoxine	1	(2.2)	0	(0.0)
Sulfamethazine	2	(5.4)	9	(19.8)
Sulfamerazine	1	(2.2)	0	(0.0)

UMI = Unidentified microbial inhibitors

Drug distribution and use: Operations, sources, labeling—In types of operations involved in residue investigations, feedlots (cattle) composed 11.4% of the operations that involved a veterinarian. All reports that involved feedlots (cattle) indicated that the veterinarian was the source of drugs administered. Other classes of operation included dairy farms, on-farm producers, buyers and dealers, and animal haulers. Veterinarians and lay channels shared equally as sources of drugs for these operations.

When drug products were available for inspection, they bore descriptive labeling in 82.9% (veterinary source) and 95% (lay source) of reports that were identified in the source-identified subset of reports. The label was considered by the field investigator to be appropriate for 76.7% (veterinary source) and 89.5% (lay source) of the drug products identified. The written or verbal orders of a veterinarian usually were considered unnecessary by the field investigator when the drug was purchased through lay channels, although written and verbal orders were documented in a limited number of such reports. When a veterinarian was identified as the source of the drug, written orders were given 47.7% of the time and verbal orders were given 67.7% of the time. In 13.6% of these reports, both verbal and written orders were given.

Market class—As stated previously, cows, veal calves, and barrows and gilts were the market classes most often associated with drug residues in both the FDA/CVM and VDACS reports. For FDA/CVM data, when source was known, a veterinarian was most likely to be involved, either as the source of the drug or as its administrator, in violative residues of cows (55.8%), bob veal (14%), calves of unspecified type (9.3%), and steers (6.9%) were the next most likely. Lay distribution channels were still important sources of violative residues in cows (36.7%), bob veal (30.6%), and barrows and gilts (16.3%).

Identifiable cause—Proportions of various identifiable causes of drug residues were roughly the same, regardless of drug source. Exceptions included lack of knowledge of withdrawal time (less frequent for lay-source drugs), exceeded dose (only

listed when veterinarian was the source), and unapproved use (only listed for lay-source drugs).

Responsibility—Whether the drug was obtained from a veterinarian or another distributor, overwhelming responsibility was assigned to the producer. When there was no veterinary involvement, 81.3% of the residues were the responsibility of the producer. When veterinarians sold the drug product, 63% of the records still indicated that the producer was responsible. Veterinarians did bear sole responsibility 12.5% of the time, and shared it with the producer an additional 8.3% of the time. In no case was a veterinarian considered to be responsible when the drug was purchased from someone else.

Discussion

Drug and Drug Product

Before discussing causes and responsibility, as suggested by the field investigations, it is important to consider the accuracy with which they represent the whole population of food animals. Our estimate for the population incidence of specific drug residues is taken from the USDA/FSIS Domestic Residue Databooks for the years 1983 to 1986.[2-5] For this purpose, we include only data derived from the USDA/FSIS Monitoring Program. The monitoring program "is designed to provide profile information on the occurrence of residue violations in specified animal populations on an annual national basis. The focus of the program is on violations; therefore, only compounds with tolerances or action levels are included in the monitoring plan. Monitoring information is obtained through a statistically based selection of random samples from animals under inspections that appear healthy."[6] Trend analyses and population estimates have been published by FSIS personnel.[7] To date, our review of published USDA monitoring and surveillance data concurs with this report, which emphasizes a limited lumber of problem market classes. For our purposes, we sought to compare the incidence of generic names and market classes relative to each other, rather than to estimate total incidence within a population. We chose to treat the 4 years of monitoring data as one set and to report a single incidence for segments of the food animal industry of interest to us. Although the USDA/FSIS Monitoring Program is conducted so that statistical analysis can be completed, it is not our intent to represent that this information is a statistical summary of population incidence. We simply use it as an independent assessment of the same population that we studied and appreciate that it is broader in scope.

The incidence of individual antibiotic and sulfonamide residues detected by the USDA from 1983 to 1986, along with similar figures from the FDA/CVM and VDACS studies, are listed in Table 12. In order to give perspective to our study of FDA/CVM-sponsored investigations, antibiotic and sulfonamide rates were compared separately. This separation was necessary because the antibiotic and sulfonamide data from the USDA publications were gathered in independent monitoring programs. The FDA/CVM and VDACS data include a larger proportion of penicillin residues than do the USDA data. Likely, this reflects the emphasis on injectables and cows as a market class that we described earlier. Sulfamethazine is underrepresented in FDA/CVM reports, probably for the same reason. The USDA/FSIS data probably are representative of the true population; we believe our compilation is a reasonably accurate reflection of the incidence for specific residues and the factors discussed here.

Table 12—Frequency of antimicrobial residues determined for FDA/CVM and VDACS field investigations and for the USDA Monitoring program for 1983 to 1986 (results expressed as percentage of antibiotic or sulfonamide residues observed)

Residue	FDA/CVM (%)	VDACS (%)	USDA (%)
Antibiotics			
Penicillin	16.9	20.3	9.4
Streptomycin	26.1	29.7	40.6
Tetracycline	4.1	3.1	6.3
Erythromycin	1.0	1.6	0.8
Neomycin	11.3	6.3	33.5
Oxytetracycline	11.8	10.9	4.7
Chlortetracycline	1.5	4.7	2.3
UMI*	11.3	15.6	22.7
Gentamicin	6.7	7.8	0.8
Sulfonamides			
Sulfamethazine	63.4	88.2	89.8
Sulfathiazole	2.4	5.8	6.2
Sulfadimethoxine	9.7	0.0	3.5

UMI-Unidentified microbial inhibitors.

Drug Distribution and Use

Hypothesis: Drug residues are a function of the sales volume of the drug, confounded by pharmacologic factors including slow absorption from injection sites, extremely prolonged elimination, and recycling of the drug from bedding and waste.

Likely, the incidence of a given drug or drug product in this study is influenced by its share of the market. The source of information we used to assess market share is the Michigan National Animal Health Monitoring System (NAHMS) report for 1987.[8] By extracting data from a survey of drug use in cattle of all ages and a variety of diseases (including gastrointestinal problems, respiratory problems, lameness, metabolic or nutritional, multiple systemic, and diseases of organs of special sense) we determined that penicillin (51.5%), streptomycin (15.1%), tetracyclines (13.8%), sulfonamides, (14.2%) and neomycin (5.3%) were the most commonly used antimicrobials in cattle. In calves, ranking was different, but included sulfonamides (31.7%), penicillin G (31.3%), tetracyclines (16.3%), gentamicin (8.3%), streptomycin (8.3%), and spectinomycin (4%). Additionally, a survey of dairy farms conducted by the Consumer

Protection Division of the Colorado Department of Health found the following drugs to be most common: penicillin G (70% of 70 dairy farms surveyed), sulfonamides (70%), oxytetracycline (68%), cephapirin (49%), and tylosin (38%).[9] It seemed a reasonable assertion that the presence of a drug on the farm was an indication of its use.

The incidence of residue violations investigated in the FDA/CVM and VDACS studies is presented in Table 1. Streptomycin, penicillin G, sulfonamides, tetracyclines, and neomycin were the most frequently reported violations in the FDA/CVM and VDACS reports.

We expect that the frequency of violations would also parallel total sales for both lay and "ethical" distribution channels (few of these were Rx) if such information were readily available. However, there is also an association between incidence and the availability of long-acting or sustained-release products. Furthermore, both streptomycin and neomycin have unusually long elimination half-lives from kidney tissue, which contributes to the potential for residues. The contribution of pharmacokinetic behavior of the specific drugs involved remains to be evaluated critically.

A complete review of pharmacokinetic causes of drug residues is beyond the scope and intent of this report. However, a brief listing of some of these associations is in order. It is known, for example, that sulfamethazine residues may be caused by failure to clean feeding equipment (and that sulfamethazine presents a greater hazard compared with other feed additives), and recycling from a contaminated environment.[10]

Residues of aminoglycosides are known to bind covalently to tissues in the kidney and to persist for extended periods after exposure to low concentrations.[10] This could account for the increased relative incidence of streptomycin as a residue in our analyses, compared with the relative prevalence of the product in the drug-use surveys previously mentioned. Also, conventional pharmacologic wisdom suggests that these products are not absorbed after oral administration. In our study, however, 5 of 6 documented neomycin residues were associated with oral administration of the drug. This finding deserves attention in terms of frequency and relationships between residues and specific diseases, management practices, or animal age. The long elimination time for aminoglycosides may be the reason this unexpected absorption has been detected.

Procaine and benzathine penicillin G accounted for all of the penicillin residues for which trade name of the drug product was known. Each of these dose forms is preferred because of convenience. Those 2 salts of penicillin are formulated to release penicillin slowly and to allow for administration twice daily, once daily, or even every third day. This extended release is a pharmacologic enhancement of the potential for residues in the injection site and more distant tissues. We are unaware of specific studies to evaluate the effect of dose form (specifically sustained release) on the correctness of the withdrawal period specified for that dose form, using current USDA/FSIS analytic techniques.

Recommendation: Surveys of residue incidence by regulatory agencies should continue. Reliable estimates of sales volumes for food animal pharmaceuticals should be sought. Funds also should be made available for the pharmacokinetic investigations of specific drugs and dose forms. Large-scale field comparisons of alternatives to sulfamethazine should be conducted. In veal calves, residues created by oral administration of neomycin deserve particular attention. Finally, careful attention should be paid to residue incidence associated with the administration of drugs such as ceftiofur sodium (others would include amoxicillin injection, sodium ampicillin, and sodium penicillin G). Its absorption and elimination characteristics make it an attractive prototype for food animal drug development. It seems likely that drugs that are rapidly absorbed and only slightly less rapidly eliminated (within reason) should be infrequently associated with residues.

Route of Administration

Hypothesis: Certain routes or methods of administration are associated with higher than average risk of drug residues.

Most likely, the association between injectable drugs and residues is confounded by the relatively high numbers of dairy cows in this study opposed to the numbers, for example, of veal calves and market hogs in the population described by the USDA/FSIS Monitoring Program reports. Dairy cows are more likely to receive injectable medications, rather than oral, as they are more likely to receive therapeutic antibiotics (which are usually given by injection) rather than antibiotics that enhance performance (which are usually given orally). Also, a greater emphasis might have been placed on therapeutic drugs in the case selection process, or injection site lesions and associated residues might have biased the process. Finally, the relative incidence of residues from injection sites rather than other tissues is not clearly available from the investigative reports (FDA/CVM and VDACS). We hasten to point out that such information is available if one investigates each tissue in the FSIS tissue analysis database.

The rather surprising incidence of neomycin residues in calves after oral administration of the drug suggests, of course, that the calf is absorbing neomycin from medicated feed mixtures. Further evaluation of this practice is necessary to interpret

this finding. Restrictions on age or disease process or a discontinuation of the practice could be in order.

Finally, surveys of this type are useful for identifying unanticipated events such as the production of residues by feeding milk that was withheld from sale for residues. It is important to identify and eliminate similar inadvertent residue-creating situations.

Recommendation: Both population and pharmacokinetic analysis of specific routes and methods of drug administration associated with an increased risk of drug residues should be conducted. Educational efforts should be directed toward enhancing the general level of knowledge of these associations.

Market Class

Hypothesis: A limited number of market classes, namely, veal calves, market hogs, and cull dairy cows, should be viewed as problem areas.

An independent evaluation of residue incidence by market class also came from a summation of the USDA/FSIS Monitoring Program.[5] The analysis of FDA/CVM and VDACS suggests that the most prevalent groups, in ascending rank order, are cows, calves, and market hogs. Although rank order in the population analyzed by USDA was somewhat different in that calves had the highest incidence of antibiotic residues and hogs had the highest incidence for sulfonamide residues, the monitoring program confirms that veal calves, market hogs, and cull dairy cows account for most drug residue problems.

Recommendation: Special attention should be given to those market classes and operation types that lead to the majority of drug residues in food animals. Regulatory efforts and those of veterinary and producer organizations should be targeted at specifically identified industry segments.

Causes for Drug Residues

Hypothesis: The dominant cause of drug residues is failure to observe withholding time. In many cases, the individual responsible for the residue was unaware of the correct drug withdrawal time.

In our study, failure to follow withdrawal time was cited as a cause for the drug residue in 69.1% (FDA/CVM) and 94.3% (VDACS) of the investigations conducted when cause was known. When only those records indicating this cause were considered, the withdrawal time was allegedly unknown 50% (FDA/CVM) and 82% (VDACS) of the time. Analysis of a similar group of field investigations conducted by FDA/CVM personnel for fiscal year 1985 (hereafter referred to as FY85) revealed that 51.32% of the reports for which cause was determined listed failure to observe withdrawal time as a cause of drug residue.[11] An evaluation of records from Michigan dairy herds also supports this observation, and the percentage of cows culled before withdrawal periods elapsed was 3.76% of all cows culled during the period of study. Taken together, these findings suggest that, for some cases, current procedures for dissemination of information fail.[12] They are further supported by a survey of dairy farmers in Michigan who cited "insufficient knowledge about withdrawal periods" as the leading cause of drug residues in milk.[13]

Whoever logically should educate the animal owner often fails to do so. Whether the privately practicing veterinarian, the drug company, the wholesale or retail distributor, the feed mill, or the FDA/CVM should be accountable in any given case is not important. The fact is, the owner of the animal often does not know the withdrawal time. This finding opens a window of opportunity for the private veterinary practitioner, who is the most logical source of drug information for the food animal producer. A system that identifies this relationship for the producer, rewards the producer and veterinarian for their mutual participation, and prepares the veterinarian for the role would be of benefit to fill this gap.

Conversely, of course, the known withdrawal time was known and disregarded in 50% (FDA/CVM) and 18% (VDACS) of the reports. Even when withdrawal times are known, poor to mistaken records, incorrect animal identification, or simple inattention will lead to a few violations. Finally, intentional violations of the withdrawal period will occur. Eliminating these latter causes for residues is a more daunting challenge for the food animal industry.

Failure to follow label directions and failure to follow the directions of a veterinarian are listed as causes of residues in a substantial number of cases (Table 3). The additional significance of either finding is dubious because, as will be discussed later, failure to follow withdrawal information is the leading type of "failure to follow label directions." Further, failure to follow label directions is cited as a sole cause in only 3 records in the FDA/CVM database. This information was not a part of the FDA/CVM FY85[11] study.

Recommendation: Veterinarians, the AVMA, and food animal specialty groups should be actively involved in education of the food animal industry.

Hypothesis: Poor production practices, associated primarily with inadequate medication records, contribute to the incidence of drug residues.

In 14.5% of FDA/CVM and 20.8% of VDACS reports, poor production practices, usually poor record keeping, were cited as causes of drug resi-

dues. Of the reports analyzed for the CVM FY85 study, 9 also cited poor record keeping as a cause of drug residue. In the latter study, poor record keeping was listed as the sole identifiable cause in only 1 report, and so is considered (by the authors of the FY85 study and by us) to be a contributing, rather than a primary, cause. This association comes as no surprise to anyone familiar with the delivery of animal health care in the United States. Complete medication records (which should include dates of administration, routes and sites, numbers and sizes of doses, and approximate weight of the animal treated) have only recently become standard practice for farming enterprises. They are not universally maintained. Medication records maintained by individuals and provided at the time of sale would improve our understanding of the problem and should directly reduce the incidence of drug residues. This statement is based on the previously discussed observation that failure to observe withdrawal time, even when that withdrawal time was known, was the most prevalent cause of drug residues.

Recommendation: Educational efforts should emphasize the importance of record keeping, including efforts to identify animals from their source to their entry into the food chain.

Hypothesis: Some fraction of residues will persist despite attention to appropriate withdrawal time.

The use of the drug product was in accordance to label directions in 11 (FDA/CVM) and 4 (VDAC&S) reports in the respective databases. Experimental evidence also supports the notion that attention to published withdrawal times may not be sufficient for residue prevention. In a study of 58 lactating dairy cows, composite milk samples were evaluated 72 hours after treatment and at 24-hour intervals until the sample no longer contained antibiotic, as detected by the *Bacillus stearothermophilus* disk assay.[14] Of 10 cows treated with intramammary cephaparin[*] according to label directions, 4 had residues persisting beyond the stated withdrawal period. Although the investigators noticed that their assay was more sensitive than that used to establish the withdrawal period, their study points to a need for similar investigations of other drugs.

Although major changes in attention to withdrawal times and medication records will likely eliminate much of the drug residue incidence, drug residues will still be a problem. Biologic variability associated with the whole population of food animals will almost ensure this. Further, certain diseases (eg, inadequate renal function, simple dehydration) and drug administration practices (eg, failure to rotate injection sites sufficiently, injection into fat rather than muscle) will contribute directly to the problem. Identification of confounding pharmacokinetic factors such as bioavailability, absorption rates, selection of appropriate routes, and injection sites is an important issue.

Recommendation: Studies of the appropriateness of stated withdrawal periods should be conducted for a number of drug products used in food animals.

Hypothesis: Unapproved drug use is a minor contributing factor to the incidence of residues in food animals.

As determined in our study, only a limited subset of records (10 in all) included unapproved drug use as a cause of residues. This was listed as the sole cause in only 1 record in either study. The CVM FY85 study reported this cause in 17.11% records. Whether this was a sole or contributing cause in this larger percentage is unknown. Neither study gives a valid assessment of the direct effect of unapproved use on the incidence of drug residues.

Drug residues are a result of the failure of the elimination of the drug from the edible portions of food animals. This is consistent not only with a reasonable toxicologic and pharmacologic approach to drug residues, but is also in keeping with current regulatory posture concerning so-called extra-label use, provided that it is in the confines of an appropriate client-veterinarian-patient relationship. Unapproved use should not be considered a primary cause of illegal residues. Complete documentation of this use, including route, dose, and withdrawal time and any directions given by veterinarians, is critical information if extra-label drug uses continue as a part of food animal therapeutics.

Recommendation: Prospective analysis of residue incidence after certain extra-label drug uses should be undertaken. Further, funding should be made available for appropriate pharmacokinetic investigations of extra-label uses of pharmaceuticals in food animals.

Responsibility

Hypothesis: The owner of the animal involved is the one making decisions to treat and to sell the animals. As a consequence, the owner of the animal bears dominant responsibility for any residues that are created.

The results of this study indicate that, in the opinion of the field investigator, the owner of the animal bore responsibility for drug residues in an overwhelming majority of reports in which responsibility was established (Table 5). The FDA/CVM FY85 study did not include an evaluation of responsibility for the residue. These results are not particularly surprising. Given the association be-

[*] Ceta-Lak, Sodium Cepharin, Bristol Laboratories, Syracuse, NY.

tween withdrawal time and drug residues, the decision to sell the animal at some point after treatment likely would have the greatest overall effect. Among private operators (dairy farms and on-farm producers made up over 60% of known operations), the decision to sell may be made in consultation with others, but the decision is still their own.

In the present regulatory environment, the food animal owner will retain considerable privilege to purchase and administer therapeutic drugs. It seems a reasonable assumption that a veterinarian is in an ideal position to give counsel to the animal owner concerning appropriate indications, administration, and withdrawal period. The food animal veterinarian is the producer's most logical source for scientific information that will aid in therapeutic decision making.

Recommendation: The AVMA and the food animal specialty groups should direct considerable effort toward expanding, first, the food animal veterinarian's ability to give correct and useful scientific therapeutic guidance, and, second, the food animal veterinarian's visibility as a logical point of positive focus for the profession's efforts designed to curb drug residues.

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1987 Gross practice income attributable to veterinary service and product categories

The AVMA's 1988 Biennial Economic Survey of veterinarians included the following question: "What was your 1987 gross practice revenue for each of the following service and product categories?"[1] Twelve categories were listed: professional services (office/farm calls including examination, consultation); surgery; radiology; laboratory/diagnostics; hospitalization; vaccinations; dentistry; nonprofessional services (eg, medicated baths, dips, groomings, boardings); product sales, drugs/medications; product sales, nondrug products (eg, nutritional products, animal care supplies); mileage; miscellaneous.

The mean percentage of 1987 gross practice revenue attributable to each service and product category was computed and weighted according to the proportion of practices that indicated a percentage of revenue for each category. Results in Table 1 show mean weighted percentages; thus, percentages illustrate a composite of veterinary practice revenue for each type of practice.

Table 1—Percentage of 1987 gross practice income attributable to veterinary service categories

Service category	Large animal exclusive (%)	Large animal predominant (%)	Mixed animal (%)	Small animal predominant (%)	Small animal exclusive (%)	Equine predominant (%)
Professional services	59*	39	33	28	22	41
Surgery	3	5	11	17	16	10
Radiology	1	1	3	4	5	7
Laboratory/diagnostics	2	2	4	6	8	6
Hospitalization	†	†	3	6	6	2
Vaccinations	4	8	8	7	8	5
Dentistry	†	†	2	2	3	2
Nonprofessional services	†	1	3	7	7	†
Sales: Drugs/medications	25	35	23	14	14	13
Sales: Nondrug products	1	3	3	4	6	2
Mileage	3	4	4	2	†	6
Miscellaneous	1	2	3	3	4	5

*Weighted mean percentages to represent percentage distribution of revenue of "composite veterinary practice"
†Weighted mean percentage is <1%

Professional services accounted for the largest percentage of 1987 gross practice revenue across all practice types, ranging from 22% in small animal exclusive practice to 59% in large animal exclusive practice. Across all types of practice, professional service accounted for 29% of gross practice revenue in 1987—2 percentage points lower than reported for 1981.[2]

Sales of drugs and medications accounted for approximately 18% of 1987 gross practice income, ranging from a low of 13% for equine practice to a high of 35% for large animal predominant practice. In small animal predominant and small animal exclusive practice, drugs/medication sales were 14% of gross practice revenue. Sales of nondrug products ranged from 1 to 2% in large animal exclusive and equine practice to 6% of revenue in small animal exclusive practice.

Surgery revenue accounted for 16% and 17% of small animal exclusive and small animal predominant practice, respectively. Surgery represented 3% and 5% of revenue in large animal exclusive and large animal predominant practice, respectively.

Each of the remaining revenue categories accounted for < 10% of gross revenue.

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